

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456
Master File No. 1:01-CV-12257-PBS
Sub-Category Case No. 1:08-CV-11200

THIS DOCUMENT RELATES TO:

*United States ex rel. Linnette Sun and Greg
Hamilton, Relators*

v.

Baxter Hemoglobin Therapeutics and Baxter International Inc.

Judge Patti B. Saris

RELATORS' SUPPLEMENTAL REPLY IN FURTHER OPPOSITION
OF BAXTER INTERNATIONAL INC'S MOTION TO DISMISS
RELATORS' COMPLAINT

1. SUMMARY OF ARGUMENT

On October 2, 2009, after briefing had been completed, this Court handed down its decision in *U.S. ex rel Ven-A-Care v. Actavis*, ___ F.Supp.2d ____ 2009 WL 3171798 (D.Mass.). In *Actavis* the Court enunciated several closely reasoned principles which guide the analysis here as well. Instead of addressing these issues Baxter has fired a distracting but largely irrelevant broadside laden with random comments and innuendo having little, if anything to do with the public disclosure issue.

Baxter’s broadside fails for several reasons. First, as *Actavision* makes clear, there has been no public disclosure, so the question of whether the relators qualify as original sources is without meaning. Second, this Court’s recent decision in *U.S. ex rel Ven-A-Care v. Abbott*,¹ (Subcategory No. 06-11337 -PBS) has clarified the definition of ‘original source’, and thus

establishes that information acquired from the relator's own efforts, which is independent of any alleged public disclosure qualifies them as an original source.

Here, despite the unseemly opprobrium cast by Baxter, the facts remain that Hamilton was a customer of Baxter's and got his pricing information

2. **THERE HAS BEEN NO PUBLIC DISCLOSURE**

Baxter hopes to avoid dealing with the merits of the Relators' allegations, and has therefore filed a brief which disregards this court's recent rulings on the ambit of the 'public disclosure' defense in *U.S. ex rel Ven-A-Care v. Actavis*, ___ F.Supp.2d ____ 2009 WL 3171798 (D.Mass.). In *Actavis* the Court enunciated several principles which guide the analysis here as well:

- A. Knowing on a general level that fraud has been committed is different from knowing that a specific individual actor engaged in a specific fraudulent scheme.*4
 - (i) No particular drugs or NDCs were identified in the government reports to which defendant refers
 - (ii) No particular scheme of Baxter's was identified
- B. Size matters. Industry-wide allegations do not constitute a public disclosure unless the industry is very small. This very court too specific issue which one of the primary cases upon which Baxter places misplaced reliance – *In re Natural Gas Royalties Qui Tam Litig.*, 562 F.3d 1032, 1042 (10th Cir.2009) , pointing out that there is a world of difference between the natural gas industry in which there are only a handful of players, and the pharmaceutical industry in which there are hundreds of players filing millions of claims.

C. Baxter and the drugs at issue are not readily identifiable from the generalized discussions of averages in the reports. “Many manufacturers and drugs could be (and likely are) innocent of the conduct alleged here, and unrelated to the averages discussed in the reports. Although some of the documents pointed out by the Defendants discuss AWP and WAC in generalized industry-wide terms, none of the reports allege or disclose industry-wide wrongdoing, and the differences between AWP and actual acquisition cost are reported as average figures. Which drugs and which manufacturers caused the averages to be at the levels reported are not disclosed by any of the reports, and the Defendants and the drugs at issue are not readily identifiable from them.” *5

3. **IN THE UNLIKELY EVENT THAT THE COURT FINDS THERE HAS BEEN A PUBLIC DISCLOSURE, HAMILTON AND SUN EACH QUALIFY AS ORIGINAL SOURCES OF THE AWP ALLEGATIONS.**

In *U.S. ex rel Ven-A-Care v. Abbott*, (Subcategory No. 06-11337 -PBS) the Court clarified the definition of “original source”. That clarification makes it apparent that the relators *are* original sources of the allegations in their complaint. In *Abbott* this Court ruled that “[S]atisfaction of the ‘original source’ provision of the FCA turns on a relator having direct and independent knowledge of information underlying his allegations. ‘Direct’ generally means the information was acquired by the plaintiff through his own efforts, and ‘independent’ means that it is not derived from public disclosure.” *Id.*, at 3. Hamilton developed his information as a customer of Baxter’s and because of the relationship he had developed with First Databank manager Kay Morgan.

Hamilton worked for Express Scripts which was a “large customer” of FDB:

Q. Let me refer you to paragraph 39 of the Complaint, which is Deposition Exhibit 7. Paragraph 39 begins with the following:

"According to knowledge obtained by relator Greg Hamilton, FDB refused to accept Baxter's 'list sales price,' and instead submitted a letter stating that their list price was \$1.31 and that they wanted their AWP to be described as \$1.31."

Do you see that?

A. Yes, I do.

Q. Did you provide that information to --

A. Yes, I did.

Q. And was that information provided to you by Kay Morgan?

A. Yes, it was.

Q. How is it that you had a conversation with Kay Morgan about Baxter?

A. Kay called me and asked if I had any idea why Baxter would be submitting information that they knew was in a format that was unacceptable.

Q. When did this communication take place?

A. I don't remember exactly. I think it was -- I'd have to go back and look at the dates. I just don't remember. But it was -- it was, I believe, within days of her having received the letter from Baxter.

Q. Do you know why Kay Morgan called you?

A. I can only speculate.

Q. What do you think?

A. I mean, I don't know.

Q. She didn't tell you why she was calling you?

MR. KLEIMAN: Calls for speculation. Go ahead.

BY THE WITNESS: I'm just saying I can -- I can only guess.

BY MR. JACKSON: What's your guess?

A. My guess is that Kay believed I was a knowledgeable person particularly about the plasma industry and about the factor industry. Kay and I

had had several conversations about AWP's, about the industry. I was introduced to her by her superiors. There was some issue -- Express Scripts is a large customer of First DataBank. And I was at a meeting with the Chief Operating Officer, Chief Financial Officer, some folks like that from First DataBank at Express Scripts, and I brought up some issue, I don't know what it was, but I know that three or four of us scurried off into a separate conference room because they were concerned about it, and they picked up the phone and called Kay Morgan. And we got on a conference call, and we discussed whatever that particular issue was, and they asked her to work with me to resolve it.

From that time forward every so often we would talk. I'd call her or she'd call me just about, you know, things that were going on in the industry and whatever else.

So, I think that when she received a letter as she described from Baxter, that as she described it, it said, "We'd like our AWP to be \$1.31 and our list price is \$1.31," she was, like, "They know that I can't accept AWP's anymore. They know that. I deal with Baxter all the time."

Q. She said that?

A. Yes. And she said, "I know that they know that, and they know I need a WAC, not this list price thing. I need a WAC. So, why are they doing this?"

And she was calling me up, trying to get -- you know, trying to get an opinion as to why she was receiving this type of communication from Baxter.

Hamilton Deposition, 43:3 - 45:24

Similarly, Linnette Sun explained how her own comparison of First DataBank's pricing with the Red Book's pricing led her to discovery parts of the same scheme:

Q Can you explain to me this First Data Bank thing that you're referring to when I referred you to Exhibit 3?

A Yeah. I've been working in pricing reimbursement and reporting pricing to First Data Bank for quite a long time. I mean even before I came to Baxter. When we were trying to determine the price for Advate, the new blockbuster, I connected with First Data Bank and noticed there was a discrepancy between the Redbook and First Data Bank, meaning, you know, First Data Bank added another 25 percent on top of Baxter's AWP price. And I knew First Data Bank was referred -- was used by many Government payors and private payors, so I brought that up to Baxter's core pricing team and said --

saying, look, on top of very inflated AWP price, First Data Bank was putting another 25 percent on top of that making the margin even bigger.

So it was -- I was really concerned. Michael Bradley and other team members told -- their kind of argument was First Data Bank was not used by many payors. And so I contacted First Data Bank -- I had all these E-mail, like a chain, but Baxter didn't allow me to have any of those when I left. So I contacted First Data Bank, the manager there, and he wrote me -- I also had my consultant then, we both private payors in the U.S. use First Data Bank as their reimbursement rates, including VA.

So I forwarded that E-mail to John Park, if I remember correctly, Nick Poulis, my supervisor, and a consultant then, and they scheduled a meeting with me and Larry Guiheen who was the President of the Bioscience Division.

Q You said you connected with someone at First Data Bank?

A Yes.

Q Who did you connect with?

A I can't remember the name now, but he was the selling -- kind of like a manager, geographic manager for the area.

Q So it was a male, not a female?

A Yeah, it's a male.

Q And what, did you ask that person some kind of questions?

A Yes. I said -- you know, I can't remember the exact E-mail, but basically trying to ask him, you know, if any Government payors or private payors are using that database to refer to as a reimbursement rate.

Q Okay. When did this communication take place?

A Again, I can't remember exactly date, it's been so long. It has to be between 2002 and 2003 when we were setting the Advate price.

So Nick scheduled a meeting with me, him, and Larry Guiheen, which was very high level because he was almost kind of like the CEO of this division.

He brought me in and said he seems to be aware of the problem and he said, but U.S. sales and marketing didn't want you to investigate, to stay away from it.

Q So when did you first come to understand that First Data Bank was increasing prices by 25 percent?

A A few months after I arrived at Baxter. I subscribed to First Data Bank, that database, and also had the Redbook which was a print copy of AWP prices.

Q So you compared --

A The two.

Q -- Redbook against --

MR. UDDEN: You've got to let him finish because otherwise when you see the record, it will be very -- so try and let him finish the question before you answer.

Q So in order to do this evaluation, you compared the data published in Redbook to the data published by First Data Bank and you determined that there's a 25 percent increase?

A Uh-huh.

Q Is that correct?

A Yes.

Sun Deposition, 114:19 – 118:13¹

“The relator need not have direct and independent knowledge of every detail or element of his complaint . . . A relator satisfies the requirement if he has ‘direct and independent knowledge of any essential element of the underlying fraud transaction. *United States ex rel Springfield Terminal Ry. Co. V. Quinn* 14 F.3 645, 657 (D.C. Cir. 1994) As numerous courts have noted, the statute requires only that the relator be “an” original source, not “the” original source.” *Id.*, at 3 – 4.

¹ It is of no consequence that Baxter fired Sun *before* Advate received it’s final approval. Sun’s testimony makes it clear that Baxter was working on Advate pricing in anticipation of the approval.

Hamilton and Sun each possess such knowledge. Hamilton's (as to AWP) comes from his work for a Baxter Customer (just as Ven-A Care learned of Abbott's fraud because it was a customer of Abbott's). Sun's came from her work at Baxter. Relators' possession of information which "was not public [but] was available only to participants in the pharmaceutical industry" through which the scheme could be detected. *Id.* at 4.

4. **HAMILTON'S KNOWLEDGE OF BAXTER'S REBATE CALCULATIONS, COMBINED WITH HIS UNDERSTANDING OF HOW THE INDUSTRY OPERATES IS A SUFFICIENT FOUNDATION FOR HIS CONCLUSION THAT IT WAS VERY UNLIKELY FOR BAXTER TO BE ABLE TO ACCURATELY REPORT IT'S BEST PRICE TO CMS.**

As a customer of Baxter's Hamilton developed intimate knowledge of Baxter's rebate structure.

Q. I show you what has been marked as Deposition Exhibit 10. Have you ever seen Deposition Exhibit 10 before?

A. Yes, I have.

Q. What is this document?

A. This is an Excel spreadsheet provided to me by Baxter when again I was with Express Scripts. If you notice, at the top it says, "Curascript." Curascript is a division of Express Scripts. It's a specialty pharmacy. And this spreadsheet reflects a contract that existed between Baxter and Curascript for the purchase of Baxter products.

Q. How is it that -- did you take this document with you when you left Express Scripts or Curascript?

A. Well, I had it in my possession. I don't know if that's the same as "took with."

Q. Right. Was it your practice to take documents with you when you left an employer?

A. It was my practice to work out of my home. Particularly from '04 to '06 working for Express Scripts I worked out of my home. And as such, I had various documents and working materials in my home.

This happened to be one of them.

Q. Was this document used in providing input to the Complaint in this matter?

A. To some extent, yes.

Q. How?

A. This document was used to demonstrate that Baxter did engage in rebate contracts.

Q. Okay. Is there anything wrong with engaging in rebate contracts, a pharmaceutical company having rebate contracts?

A. Not at all.

Q. So, again, how was paragraph 10 used in conjunction with the Complaint, if you know?

MR. KLEIMAN: Do you mean Exhibit 10?

M R. JACKSON: Yes, I do. I'm sorry. Exhibit 10.

BY THE WITNESS: Oh, okay. I can only repeat what I just --my previous answer. It was used to illustrate that Baxter did indeed participate in rebate contracts.

I suppose I could go even one step further. It also shows the manner in which Baxter calculated or adjudicated these rebates, and that this was done, obviously, on an Excel spreadsheet. So, this is separate and apart from the standard order entry process, debit and credit inventory system that Baxter would use and, therefore, separate and apart from its Medicaid Administrative Program.

Q. You've never worked for Baxter, correct?

A. That is correct.

Q. So, you don't know how this spreadsheet that is Deposition Exhibit 10 interacts in any way with Baxter's order entry process, do you?

A. I know how the industry works. And I don't believe Baxter's order entry process is on an Excel spreadsheet, especially when this Excel spreadsheet was calculated incorrectly and I had to correct it.

Q. I'm asking you do you know how -- do you know how Baxter's order entry system works?

A. Not specifically, no.

Q. And do you know how Baxter's Excel spreadsheet that you identified as Exhibit 10 works with Baxter's order entry system?

A. I do not know if it works with it or if it -- how it works with it. I don't even know if it does work with it.

Q. You have no knowledge of the internal workings at Baxter vis-à-vis calculations of rebates or pricing, correct?

A. That is correct.

Let me correct that. When you say "calculations of rebates," do I have any knowledge of how Baxter calculates rebates internally? Well, the fact that as a customer I get my rebate information that comes off an Excel spreadsheet tells me I know spreadsheet-driven, and the fact that when I went through this and recognized there were mistakes on it and went back to the Baxter rep and said, "Hey, you've got mistakes," as a matter of fact, they were in Curascript's favor, "you've made some errors on here,"

He responded with, "Oh, yeah. The guy running the Excel spreadsheet made a mistake. He moved a field over. I'll have him correct it," that tells me something about how they're adjudicating their rebates.

Hamilton Deposition, 49:22-53:10

5. **A MOTION ON JURISDICTIONAL ISSUES IS NOT THE PROPER VEHICLE FOR RESOLVING THE CONTROVERSY OVER THE VOLUME COMMITTED CONTRACTS. LEAVE SHOULD BE GRANTED TO AMEND TO ASSERT THAT THE CONTRACT AS STRUCTURED VIOLATE THE ANTI-KICKBACK STATUTE.**

Although Baxter directed much invective at the allegations concerning Baxter's Volume Committed Contracts program, Baxter itself has admitted that "... a number of the complaints refer to alleged improprieties concerning volume discounts, similar to the Best Price allegations related to 'Volume Committed Contracts' in Relators' Complaint ¶ 51. See, e.g., MCC ¶ 165 (referring to 'volume discounts, rebates, off-invoice pricing, free goods,' etc.); (Nassau County

Complaint) ¶¶ 95, 96 (discussing alleged improprieties associate with volume discounts, wholesaler chargebacks, and volume-based rebates).” Defendants’ Motion to Dismiss, pp. 5-6.

It is apparent that Ms. Sun is far from the only litigant to take issue with this practice.

Allowing leave to amend to properly plead that the same acts as originally alleged violate the the Anti Kickback Statute is proper under F.R.C.P. 15, and does not prejudice Baxter in any measurable way. In *Actavis* defndant similarly argued that they were somehow prejudiced by a delay. This Court noted that “any delay in unsealing the case was caused by the Government exercising its right to obtain lawful extensions of the seal to investigate what is an incredibly large and complex scheme. The Defendants have produced no evidence that the extensions were improper or prejudicial, and they have provided no evidence that they were harmed in their ability to gather evidence or prepare their defense”.

Id., at *9.

Similarly, amendment should be allowed for Relators to meet the pleading standard announced by this Court in *In re Pharmaceutical Industry Average Wholesale Price Litigation* 478 F.Supp.2d 164, which was handed down two years *after* Relators filed their complaint in this matter.

Respectfully submitted,

Dated: February 4, 2010

/s/ Mark Allen Kleiman
Mark Allen Kleiman
2907 Stanford Avenue
Venice, CA 90292
Telephone (310) 306-8094
Facsimile (310) 306-8491
Counsel for Relators

CERTIFICATE OF SERVICE

I hereby certify that I, Mark Kleiman, an attorney, counsel for Relators, electronically filed the foregoing **RELATORS' SUPPLEMENTAL REPLY IN FURTHER OPPOSITION OF BAXTER INTERNATIONAL INC'S MOTION TO DISMISS RELATORS' COMPLAINT**, with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on February 4, 2010. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties. In addition, the individuals listed below were served via U.S.

BY: /s/ Mark Kleiman

Mark Allen Kleiman
2907 Stanford Avenue
Venice, CA 90292
Telephone: (310) 306-8094

Edwin Winstead
Assistant United States Attorney
1225 Seventeenth Street
Suite 700
Denver, CO 80202

Dustin McDaniel, Attorney General
Office of the Arkansas Attorney General
200 Tower Building
323 Center Street
Little Rock, AR 72201-2610

Greg Abbott, Attorney General
Office of the Texas Attorney General
Capitol Station
P.O. Box 12548
Austin, TX 78711-2548

Martha Coakley, Attorney General
Office of the Massachusetts Attorney
General
1 Ashburton Place
Boston, MA 02108

Lisa Madigan, Attorney General
Office of the Illinois Attorney General
James R. Thompson Center
100 W. Randolph Street
Chicago, IL 60601

Kenneth T. Cuccinelli, Attorney General
Randall L. Clouse, Director
Medicaid Fraud Control Unit
Office of the Virginia Attorney General
900 E. Main Street
5th Floor
Richmond, VA 23219

Joseph R. Biden, III, Attorney General
Office of the Delaware Attorney General
Carvel State Office Building
820 N. French Street
Wilmington, DE 19801

Robert E. Cooper, Jr., Attorney General
Office of the Tennessee Attorney General
500 Charlotte Avenue
Nashville, TN 37243

Catherine Cortez Masto, Attorney General
Office of the Nevada Attorney General
Old Supreme Court Building
100 North Carson Street
Carson City, NV 89701

Mark J. Bennett, Attorney General
Office of the Hawaii Attorney General
425 Queen Street
Honolulu, HI 96813

Bill McCollum, Attorney General
Office of the Florida Attorney General
The Capitol
PL-01
Tallahassee, FL 32399-1050

Edmund G. Brown, Attorney General
Brian Frankel
Office of the California Attorney General
1300 I Street
Suite 1740
Sacramento, CA 95814

Peter Nickles, Attorney General
Office of the DC Attorney General
441 4th Street, NW
Suite 1145S
Washington, DC 20001

James D. Caldwell, Attorney General
Office of the Louisiana Attorney General
P.O. Box 94095
Baton Rouge, LA 70804-4095

Mark Shurtleff, Attorney General
Office of the Utah Attorney General
State Capitol
Room 236
Salt Lake City, UT 84114-0810

Gary King, Attorney General
Office of the New Mexico Attorney General
P.O. Drawer 1508
Santa Fe, NM 87504-1508